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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,066	05/29/2001	Thomas R. Fuerst	4600-0293.20	7789
22918	7590	06/02/2004	EXAMINER	
PERKINS COIE LLP			FOLEY, SHANON A	
P.O. BOX 2168			ART UNIT	
MENLO PARK, CA 94026			PAPER NUMBER	

1648

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/769,066

**Applicant(s)**

FUERST ET AL.

**Examiner**

Shanon Foley

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-14 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 18 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Foley.

#### ***Request for Continued Examination***

The request filed on February 5, 2004 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/769,066 is acceptable and a RCE has been established. An action on the RCE follows.

Applicant has amended claims 11-13 and added new claim 25. Claims 11-14 and 18-25 are pending in the application. Claims 19-24 remain withdrawn from consideration due to non-elected inventions. Claims 11-14, 18 and 25 are under consideration.

Applicant is persuasive with respect to the rejection under 35 USC 102(e).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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The claims are drawn to a substantially isolate nucleic acid encoding an amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16 or an amino acid sequence having the amino acid terminus of SEQ ID NOs: 15 or 16 and a deletion of up to 24 amino acids from the carboxy terminus. The claims also encompass amino acid sequences that are at least 70% homologous to any of the aforementioned sequences. The claims do not require that the sequences possess any particular distinguishing feature, biologic activity, or conserved structure. Therefore, the claims are drawn to a genus of sequences that are defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure of the sequences that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical

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structure of the encompassed genus of sequences, given that the specification has only described SEQ ID NOs: 15 and 16 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only substantially isolated nucleic acids encoding an amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16 or an amino acid sequence having the amino acid terminus of SEQ ID NOs: 15 or 16 and a deletion of up to 24 amino acids from the carboxy terminus of SEQ ID NOs: 15 or 16, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by (Genseq database accession no: AAQ27436. First entry: February 5, 1993 of Patent No: JP04200388-A).

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It has been previously determined that the instant claims receive the benefit of the filing date of parent application 08/327952, viz. October 24, 1994. Therefore, AAQ27436 is applicable under 35 U.S.C. 102(b).

Claim 11 is drawn to a substantially isolated nucleic acid sequence encoding a polypeptide derived from the carboxy-terminal 549 amino acids of HEV ORF2, wherein the amino acid sequence is selected from SEQ ID NO: 15 and has a sequence homology of at least 70%.

The nucleic acid sequence of AAQ27436 is 98.11% similar to the instant SEQ ID NO 15, see the sequence alignment provided and "Percent Similarity".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genseq database accession no. AAQ27436 as applied to claim 11 above, and further in view of McLinden et al. (US 5,294,548).

Claims 12-14 and 18 are drawn to a baculovirus expression vector in a method used to produce an HEV polynucleotide antigen in a baculovirus host cell.

See the sequence alignment of AAQ27436 above. The alignment does not teach a method of producing more protein in a baculovirus expression system. However, McLinden et

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al. teach a method of producing a hepatitis A protein in a baculovirus expression system, see example 10 beginning in column 21 for example.

One of ordinary skill in the art at the time the invention was made would have been motivated to express the sequence of AAQ27436 in the baculovirus expression method of McLinden et al. to produce larger quantities of protein, see column 4, lines 9-13 of McLinden et al. for use in the immunoassay of AAQ27436, see the brief description provided in the sequence alignment. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing large quantities of the sequence of AAQ27436 in the method of McLinden et al. because McLinden et al. teach production of a hepatitis protein from a sequence and AAQ27436 teach the a non-A, non-B hepatitis sequence. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention as made, absent unexpected results to the contrary.

#### ***Allowable Subject Matter***

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shanon Foley  
Patent Examiner, 1648